## ART 34 AMDT

## **CLAIMS:**

- 1 1. A stable pharmaceutical composition for oral administration of ACE inhibitor(s)
- 2 comprising
- i) a core; coated with a layer of ACE inhibitor(s).
- 4 ii) a seal coat on the core; and
- 5 iii) an ACE inhibitor layer which is free of plasticizers and organic solvents.
- 1 2. The composition of claim 1 wherein the ACE inhibitor is selected from the group
- 2 consisting of ramipril, quinapril, enalapril, spirapril, lisinopril and benazepril.
- 1 3. The composition of claim 1 wherein the layer of ACE inhibitor(s) comprises film
- 2 forming polymer.
- 4. The composition of claim 3 wherein the film forming polymer is selected from the
- group consisting of hydroxypropylcellulose, hydroxypropylmethylcellulose,
- 3 hydroxyethylcellulose, ethylcellulose, cellulose acetate, polyvinylpyrrolidone, gelatin,
- 4 a combination of microcrystalline cellulose and carrageenan, and a combination of
- 5 polyvinyl alcohol and polyvinylacetate.
- 5. The composition of claim 1, wherein the core is a compressed tablet.
- 6. The composition of claim 1, wherein the core comprises a sugar sphere or nonpareil
- 2 seeds.
- 7. The composition of claim 5 or 6, wherein compressed tablets, sugar spheres or
- 2 nonpareil seeds are filled into hard gelatin capsules.
- 1 8. The composition of claim 1, wherein the core is inert.
- 9. The composition of claim 1, wherein the core has a pharmaceutically active substance
- other than the one which is susceptible to degradation by mechanical stress.
- 1 10. The composition of claim 9, wherein the pharmaceutically active substance is
- selected from the group consisting of hydrochlorothiazide, piretanide, and
- 3 dihydropyridines







- 1 11. The composition of claim 1 wherein the seal coat comprises film forming polymer
- 1 12. The composition of claim 11 wherein the film forming polymer is selected from the
- group consisting of hydroxypropylcellulose, hydroxypropylmethylcellulose,
- 3 hydroxyethylcellulose, ethylcellulose, cellulose acetate, polyvinylpyrrolidone, gelatin,
- a combination of microcrystalline cellulose and carrageenan, and a combination of
- 5 polyvinyl alcohol and polyvinylacetate.
- 1 13. The composition of claim I wherein the ACE inhibitor layer is further surrounded with
- 2 an outer coat.
- 1 14. A process for the preparation of a stable pharmaceutical composition for oral
- administration of ACE inhibitor(s) comprising applying a seal coat on a core and
- disposing a layer of an ACE inhibitor dispersion, suspension which is free of
- 4 plasticizers and organic solvents onto the coated core.
- 1 15. The process of claim 14, wherein the layer is disposed as a coating dispersion.
- 1 16. The process of claim 15, wherein the coating dispersion is made in aqueous solvent.
- 17. The process of claim 14, wherein the dispersion is sprayed on the cores.
- 1 18. A method of treating a disorder selected from the group consisting of hypertension,
- 2 congestive heart failure, left ventricular dysfunction and diabetic nephropathy, the
- method comprising administration of a therapeutically effective amount of the
- 4 pharmaceutical composition of claim 1 to a patient suffering from such a disorder.